

## **REMARKS**

Reconsideration of the above-identified application, in view of the following remarks, is respectfully requested. Claims 1 and 2 are currently pending. No new matter is added by way of this response.

### **I. Rejection Under 35 U.S.C. § 103(a)**

The Examiner has rejected claims 1 and 2 under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,022,551 (to Jampani et al.) and U.S. Patent No. 5,965,610 (to Modak et al) in view of U.S. Patent No. 5,516,510 (to Beilfuss et al.). According to the Examiner, Jampani describes a composition comprising antimicrobial agents such as chlorhexidine digluconate (0.1-4.0%) and benzalkonium chloride (0.02-1.0%), among others, which are effective against gram negative and gram positive microorganisms when applied as a topical composition. The Examiner contends that Modak discloses an irritant-inactivating composition comprising an antimicrobial, such as, for example, benzalkonium chloride, triclosan or chlorhexidine digluconate, as well as zinc compounds such as zinc acetate, zinc gluconate, zinc oxide, zinc stearate and zinc salicylate. The Examiner also alleges that Beilfuss describes a deodorant composition comprising octoxyglycerin (0.01-20%) and an antimicrobial (e.g. chlorhexidine salts) which exhibit a deodorizing effect through antimicrobial activity, inhibition of enzymes or catalysts responsible for odor formation, and inhibition of sweat secretion. The Examiner further states that Beilfuss' formulations are effective antimicrobials against gram positive and gram negative microorganisms. According to the Examiner, it would have been obvious to a skilled artisan to combine the antimicrobial agents described by the three references to produce the antimicrobial composition encompassed by the claims of the instant application.

Applicants respectfully disagree, and submit that evidence of unobvious or unexpected advantageous properties rebuts *prima facie* obviousness, and that the presence of a property not possessed by the prior art is sufficient evidence of nonobviousness. See M.P.E.P. 716.02(a); see also *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963). The claimed invention encompasses, *inter alia*, the unexpected discovery that octoxyglycerin, when combined with a quaternary ammonium compound (e.g., benzalkonium chloride) and a second antimicrobial agent (e.g., a

biguanide), exhibits a synergistic increase in the combined antimicrobial efficacy of the three antimicrobial agents. *See, e.g.*, the specification at p. 37, ¶¶ 62 and 64.

As disclosed in Examples 3 and 4 of the instant application (*see* pp. 37-42), a composition comprising octoxyglycerin, a quaternary ammonium compound (*e.g.*, benzalkonium chloride) and a second antimicrobial agent (*e.g.*, chlorhexidine digluconate), as encompassed by the pending claims, exhibited a synergistic antimicrobial effect when the three agents were present together in the single composition. For example, as disclosed in Table 4 at page 38 of the specification, the composition comprising all three agents exhibited a synergistic effect that was greater than the additive antimicrobial effect of the three agents (*see* Table 4, wherein the synergistic effect of the three combined agents exceeded their additive effect by 5.1 log 10). Accordingly, the composition comprising the three combined agents exhibited a synergistic antimicrobial effect that was sufficient to reduce bacterial colony counts by  $10^8$  fold greater than a control composition. *See* the specification at page 38, Table 4.

Applicants note, and the Examiner acknowledges (*see* the July 7, 2008 office action at page 4), that neither Modak nor Jampani disclose a composition comprising octoxyglycerin. Further, although Beilfuss discloses that octoxyglycerin in combination with other “deo-active” ingredients (*i.e.*, deodorizing active ingredients, *see* Beilfuss at Col. 1, ll. 46-47) can cause synergistic increases in “effect” in “some cases,” no guidance is provided as to which “effects” and which “cases” such an increase can occur. *See* Beilfuss at Col. 3, ll. 38-42. For example, Beilfuss describes numerous deodorizing substances which may be combined with octoxyglycerin, but only discloses that mixtures with lower alcohols such as ethanol produce synergistic antimicrobial effects. *See* Beilfuss at Col. 3, ll. 14-37; and Col. 3, l. 31-Col. 4, l. 3. In particular, none of the formulations for which Beilfuss discloses quantifiable antimicrobial effects comprise octoxyglycerin, a quaternary ammonium compound and a second antimicrobial agent, as recited by the instant application’s pending claims. *See* Beilfuss, Table at Col. 4-5.

Applicants submit that the surprising and unexpected synergistic antimicrobial effects achieved by practicing the invention as claimed is indicative of the claims’ non-obviousness in view of the collective teaching of the cited references. Thus, Applicants respectfully request that the rejection be withdrawn.

## **II. The Double Patenting rejection**

The Examiner has rejected claims 1 and 2 on the ground of nonstatutory obviousness-type double patenting as double-patenting over claims 1-2, 6, 24-25 and 29 of U.S. Patent No. 6,846,846 ("the '846 patent"). The Examiner contends that the '846 patent is directed to an antimicrobial composition comprising synergistic effective amounts of octoxyglycerin, a quaternary ammonium compound, and an antimicrobial compound selected from a biguanide, triclosan, phenoxyethanol, an iodine compound and parachlorometaxyleneol. According to the Examiner, the claims of the instant application are not patentably distinct over the claims of the '846 patent.

Without conceding to the Examiner's contentions, Applicants respectfully submit that the appropriate action will be taken (*e.g.*, through the submission of a Terminal Disclaimer), as the Examiner indicates allowable subject matter in the instant application.

## **III. Conclusion**

In view of the above remarks, it is respectfully requested that the application be reconsidered and the claims allowed. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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